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10/092,033	03/05/2002	Stephen F. Fulghum	NLI-002AX	7761

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EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/092,033	FULGHUM, STEPHEN F.	
	Examiner	Art Unit	
	John P. Leubecker	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *12-20 and 27-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 14, 2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-11 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites a diode laser light source for producing excitation light. The invention, and thus the disclosure, is specifically directed to use of an arc lamp as the excitation light source. Note at least page 8, lines 23-24 and page 10, lines 16-18 which describe the invention as requiring an arc lamp. The only mention of a laser diode in the specification is on page 10, lines 13-16, wherein it is mention as one of two other light sources that have previously

been used. Thus, the disclosure fails to provide adequate written description of how a laser diode is part of the disclosed invention or could be used in the disclosed invention.

4. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Two types of light are referred to a "reference light" in the application: normal white (e.g. red,green,blue) light used for the normal visible light image and red/infrared light used as a reference light for comparison purposes. Both are confusingly mentioned using the term "reference light" but only one is disclosed as being emitted simultaneously with the excitation light. The true reference light of red/infrared wavelengths is the one that can be emitted simultaneously with the excitation light. The reference light including red, green and blue wavelengths (which corresponds to the normal image light mode) is not disclosed as being capable of being emitted simultaneously with the excitation light.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-6, 8-11, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. (U.S. Pat. 5,749,830) in view of Poindexter et al. (U.S. Pat. 5,979,523).

Referring mainly to Figure 51, Kaneko et al. disclose a laser light source (904) for producing light having a wavelength in a range of 300 to 420 nm (col.7, lines 35-38), a second light source (905), an optical combiner (915,916), a common optical path coupled to an optical guide (901), a single image detector (902), and a data processor (908,913). Kaneko et al. fails to explicitly disclose that the laser light source is a diode laser light source (instead, a He-Cd laser is exemplified as being just one source that operates in the necessary wavelength range). However, certain diode laser light sources are known to operate in the wavelength range of 300 to 500 nm. Poindexter et al. is just one example of a teaching that a GaN diode laser, which operates within the claimed wavelength range, is a suitable source of excitation light (col.2, lines 57-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used any known suitable light source (including the one taught by Poindexter et al.) that operated within the range of 300-500 nm in the Kaneko et al. device as a matter of design choice. One would be motivated to use a diode laser over a conventional laser or other light source due to its efficient, low power and stable emission of light.

Furthermore, the transmission of light by the light sources of Kaneko et al. are enabled/disabled (e.g., operable) by signals from a timing controller (907) and computer (941), both of which would anticipated a control system.

As to claim 2, note superimpose circuit (928, col.62, lines 61-67). As to claim 3, note that the solid state imaging element (902) can be a CCD (note at least col.21, line 64). As to

claim 4, note (831) in Figure 49. As to claim 6, note column 63, lines 19-27. Since the excitation light and reference light are sequentially transmitted (by 916), claim 8 is met. As to claim 9, note red filter in RGB filter (918). As to claim 10, note (920). As to claim 11, since the reference and excitation lights share a common optical path, they have the same angular distribution. As to claim 21, a CCD is pixellated. As to claims 23 and 24, obvious choice of the diode laser source as taught by Poindexter et al. would meet these limitations.

As to claim 5, note that the CCD is at the distal tip of the endoscope. Kaneko et al. also discloses in Figure 51 the situation where a sequential RGB light (note filter 918) is used with a monochromatic CCD. However, earlier in the reference, Kaneko et al. explicitly teaches that use of a simultaneous RGB (white) light with a color CCD is alternatively and equivalently used to produce the same results (note Figures 4a and 4b, col.9, lines 6-9 and col.12, lines 20-33). Since both methods are known in the art, it would be within the level of ordinary skill in the art to use either as an alternative to one another, and Kaneko et al. contemplates both for use in the disclosed fluorescence endoscope system, it would have been obvious to one of ordinary skill in the art to have modified the embodiment of Figure 51 to have used a color CCD. Where there is a limited universe of potential options, the selection of any particular option would have been obvious to one of ordinary skill in the art. In re Jones, 412 F.2d 241, 162 USPQ 224 (CCPA 1969).

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. in view of Poindexter et al. and further in view of Perelman et al. (U.S. Pat. 6,091,984).

Kaneko et al. teach a device that uses, for example a CCD, for the image sensor but fails to disclose all other known image sensors that can alternatively used. Perelman et al. teaches what is known by all of those of ordinary skill—the alternative use of either a CCD or CMOS image sensor (note col. 4, lines 26-34). CMOS technology is not new and in certain arrangements has cost advantages and improved functionality over CCD technology. It would therefore have been obvious to one of ordinary skill in the art to have used a CMOS image sensor instead of a CCD image sensor for the reasons set forth above.

8. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaneko et al. in view of Poindexter et al. and further in view of Groner et al. (U.S. Pat. 6,104,939).

Kaneko et al. provides reference to a xenon light source *as an example* (note col.7, line 31). Groner et al. also teaches use of a xenon light source in addition to many alternatives including a mercury arc lamp and a laser diode (col. 24, line 55 to col.25, line 4). It would have been obvious to one of ordinary skill in the art as a matter of design choice to use any known alternative type of light source as taught by Groner et al.

Response to Arguments

9. Applicant's arguments filed August 8, 2006 have been fully considered but they are not persuasive.

Regarding the rejection 35 U.S.C. 112, first paragraph, concerning claims 1-11 and 21-26, Applicant suggests that the Examiner has ignored the "teaching regarding numerous other embodiments using other light sources". The Examiner has not ignored anything, but instead has

interpreted the specification as any reasonable person would. Contrary to Applicant's contention, the reference to Wang et al. at page 5, lines 4-9 of the specification is referring to the *wavelength of light* for the preferred embodiment:

> "In a preferred embodiment, near ultraviolet light is chosen as the excitation wavelength, as described in Wang, et al. US Provisional Application No. 60/072,455" (page 5, lines 4-5).

Thus, Applicant's specification in no instance refers to the argon-ion laser as a preferred embodiment as the UV source. Accordingly, mention of other light sources (i.e., laser diodes) in correspondence with the Wang et al. reference does not suggest or imply use of these light sources in the present invention.

Instead, Applicant states:

> "The systems in accordance with the present invention uses a mercury arc lamp as a source of UV excitation with a spectral band around the 365 nm mercury line. The mercury arc source is smaller, and less expensive than the argon-ion laser, requires relatively little power and is air-cooled." (page 10, lines 16-20).

This would imply to the reasonable person that argon-ion lasers and laser diodes have been considered in the art but are not for use in the present invention.

As Applicant has pointed out at page 12, lines 2-4:

> "The CCD detector in this type of endoscope is sensitive to all wavelengths between 400 nm and 700 nm, but is insensitive to UV excitation wavelengths around 365 nm which are used to excite the autofluorescence.".

This would support use of the mercury arc lamp (spectral band around 365 nm) but not support use of a GaN laser diode operating a wavelengths in the range of 380 nm to 420 nm. This is the basis for the Examiner's rejection under 35 USC 112, first paragraph. Although the laser diode is mentioned with respect to prior knowledge, Applicant has not provided any support or

enabling embodiment that would include a laser diode as the light source. Thus, the written description is lacking. It would appear that the laser diode would not be appropriate for the CCD used by Applicant since an overlap of excitation wavelengths with the imaging wavelengths could cause interference or degradation of the image.

And if Applicant wants to rely on the Wang et al. disclosure (US 60/072,455) as teaching that the range of 300-420 nm is acceptable for the excitation light (as erroneously reported on page 5, lines 6-9), it must be pointed out what this reference really teaches:

> "In addition, it is surprising that reflected 370 nm excitation light did not completely flood the CCD, obscuring the fluorescence signal. This results from the fact that the CCD spectral response falls off to zero quickly at wavelengths below 400 nm." (within first full paragraph of page 3 of US 60/072,455).

This clearly supports Applicant's intention of using a mercury arc lamp and would teach against use of a light source that produced wavelengths greater than 400 nm (e.g., GaN laser diodes). Without a specific reference to how a diode laser would be incorporated into the invention (i.e., differences in structure and/or function), the description is deemed to be deficient.

Therefore, the Examiner has maintained the rejection of claims 1-11 and 21-26 under 35 USC 112, first paragraph.

Regarding the rejection of claim 7 under 35 U.S.C. 112, first paragraph, Applicant cites a portion of the specification (page 79, lines 12-13 and lines 29). Since the specification does not have 79 pages, it is unclear as to what Applicant is referring. In any event, it is noted that the simultaneous transmission of light is not at issue—what is at issue is *which* light is simultaneously transmitted. As previously pointed out, the specification confusingly refers to both the visible image light (RGB) and the nominally red reference image light as "reference

light". Claim 1 requires the "reference light" to include red, green and blue wavelength bands and be transmitted through a common optical path as the excitation light (see claim 1). The specification does refer to simultaneous transmission of the excitation and nominally red reference image light as per page 5, lines 9-19. What Applicant has not shown support for is the simultaneous transmission of the visible image light (including red, greed and blue) down a common optical path with the excitation light in the combination of elements as claimed in claims 1 and 7.

Regarding the rejection of claims 1-11 and 21-26 under 35 U.S.C. 112, first paragraph, the Examiner has previously set forth his position with respect to this issue and it is being maintained. In view of Applicant's comments, the Examiner must note that Applicant's labeling of two-line sentence mentioning a laser diode (but not describing it in relation to any other elements of the claimed invention) as an "embodiment" of the invention is not well taken.

Regarding Applicant's arguments concerning the Poindexter ('423) reference, Applicant argues that Poindexter does not provide a "teaching or suggestion in this reference that such a source could be used to induce tissue autofluorescence in the claimed range suitable for diagnostic purposes". Since the Examiner has not relied on such a specific teaching, this argument is rendered moot. The Examiner was under the impression that it was the wavelength range of the diode laser that allowed it to induce tissue autofluorescence. Applicant did not discover the wavelength range of any new diode laser. The construction and use of these were known and used in the art at the time of filing Applicant's application (remarks filed August 30, 2004, page 8, second full paragraph). So why couldn't such known sources be used?

It is noted that upon filing the RCE (October 14, 2008), no amendments to the claims have been made (even though the status modifier for claim 7 is "Currently Amended) and the arguments presented in the paper filed August 28, 2007 have been substantially repeated. Therefore, the Examiner has substantially repeated the rejections and arguments from the previous Office Action. Applicant does add remarks in reference to the rejections of claim 22, 25 and 26, but such remarks base the validity of the rejections on the alleged patentability of claim 1. Therefore, no response is required from the Examiner.

Conclusion

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/
Primary Examiner
Art Unit 3739

jpl